

Serial No. 09/091,958
Filed: June 7, 1999
Examiner Z. Fay
Group Art Unit: 1614

Remarks

Claim 1 has been amended. With this amendment, the claims pending are claims 1, 2, and 5-20. Support for the amendment to claim 1 is found in the specification as originally filed. Specifically, support for the volume limitation can be found at page 3, lines 17-20. Also, see original claim 4. Thus, no new matter is added by this amendment.

Applicants wish to make clear that the amendment to claim 1 does not restrict the dosage form to one delivered along a horizontal path or to a dosage form delivered in any particular direction. The "size sufficient" limitation applies only to the size of the stream or droplets.

Although Applicants maintain that the claims were sufficient to overcome all the prior art as they existed after their last response, Applicants have made the amendments herein to distinguish the invention even further from the art. Consequently, it is respectfully submitted that the claims as amended are clearly nonobvious over the references relied on by the Examiner, U.S. Patent No. 4,158,361 (Kotuby) and UK Patent Application GB 2 255 918 (Dunne). Claim 1 requires a predetermined liquid volume in the form of a jet or stream of droplets and that substantially the entire dosage form is

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delivered to the target. The jet or each droplet "is of a size sufficient to sustain momentum along a substantially horizontal path 5 cms in length from a discharge velocity of up to 25 m/sec from the delivery device." Neither Kotuby nor Dunne teaches or suggests such a dosage form.

Whilst the Kotuby and Dunne references appear to disclose devices that deliver liquid in droplet form, there is no disclosure or suggestion of such droplets being targeted upon discharge from the treatment liquid container or that the droplets have the size required by the claims.

As discussed on page 1, lines 5-23, it is important that the dosage form have sufficient momentum to be accurately targeted, and beat the "blink response." The "blink response" is the natural reaction of the human eye to close in response to the imminent or actual impact of any item. The claims are directed to a dosage form capable of defeating the "blink response" by ensuring that the entire quantity of treatment liquid in the dosage form reaches the eye before it reflexively closes.

Both Kotuby and Dunne clearly fail to disclose or suggest the claimed invention. The claims are not therefore obvious in

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view of Kotuby or Dunne and withdrawal of the rejection is respectfully requested.

Allowance of the claims and passage of the case to issue are respectfully solicited. Should the Examiner believe a discussion of this matter would be helpful, he is invited to telephone the undersigned at (312) 913-0001.

Respectfully submitted,

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Marked-up version of claims showing changes

1. (Twice amended) A dosage form useful in ophthalmic treatment having a predetermined liquid volume of from about 3 to 20 μ l, the dosage form being a jet or stream of droplets of treatment fluid, each droplet having an ophthalmologically active compound in suspension or solution and wherein the jet or each droplet [has a momentum sufficient to sustain transmission from a delivery device to a target site within an eye] is of a size sufficient to sustain momentum along a substantially horizontal path 5 cms in length from a discharge velocity of up to 25 m/sec from the delivery device, wherein substantially the entire dosage form is delivered to the target site.